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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/904,709 | 07/12/2001 | Jeffrey H. Burbank | 53951-028 | 2940 |

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PROSKAUER ROSE LLP
PATENT DEPARTMENT
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EXAMINER

KIM, SUN U

| ART UNIT | PAPER NUMBER |
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1723

DATE MAILED: 02/28/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/904,709

Applicant(s)

Burbank et al.

Examiner

John Kim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jul 12, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 11, 15-21, 25, 29, 43, 46, 50, and 54 is/are pending in the application.
- 4a) Of the above, claim(s) 17-21, 25, 29, 50, and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 11, 15, 16, 43, and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Jul 12, 2001 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3 6) ☐ Other:

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1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-8, 11, 15-16, drawn to an extracorporeal filter or a blood processing device with a cap with multiple ports, classified in class 210, subclass 321.6.
 - II. Claims 17-21, 25, 29, 50, 54, drawn to a method for filtering blood including hemodilution method, classified in class 604, subclass 4.01.
 2. The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice cleaning dialyzer with multiple ports or oxygenating blood.
 3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.
 4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
 5. During a telephone conversation with Mr. Mark Catan on 2/24/03 a provisional election was made without traverse to prosecute the invention of Group I, claims 1-8, 11, 15-16.
- Affirmation of this election must be made by applicant in replying to this Office action. Claims

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17-21, 25, 29, 50 and 54 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second outlet for waste and ultrafiltrate and a second inlet for blood must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 15-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an outlet for waste and ultrafiltrate and/or a second inlet for blood, does not reasonably provide enablement for a second outlet for waste and ultrafiltrate and an inlet for

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blood. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-8, 11, 15-16, 43 and 46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-8, 11, 15-16, 43 and 46 are indefinite for failing to particularly point out the structural relationship between (filter media or fiber membrane) and (an inlet for blood, an outlet for waste and ultrafiltrate, an outlet port for blood, an infusion port, a second outlet for waste and ultrafiltrate or a second inlet for blood).

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. Claims 1-2, 4-8, 11, 43 and 46 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,236,586 (hereinafter referred to as Antoni et al.). Antoni et al teach a filter apparatus comprising a housing (1) having attached end caps (4) wherein each end cap has two ports located radially adjacent to each other; one end cap has an inlet (5) and an outlet (12) and the other end cap has an inlet (11) and an outlet (6) or vice versa; there is a gap (14) between the filter media (2) and the cap (4); the housing (1) contains hollow fiber filter media (2); Antoni et al teach that end caps are attached to the housing by gluing or by means of screw connection (see figure 1; col. 2, lines 61-68; col. 3, line 61 - col. 4, line 55). Use of the inlet and/or outlet for different fluids are an intended use of the apparatus and these are not given patentable weight to the structural limitation.

15. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Antoni et al as applied to claim 1 above, and further in view of U.S. Patent No. 5,820,767 (hereinafter referred to as Kane et al). Antoni et al teach that end caps are attached to the housing by gluing (see col. 2, lines 61-68). Claim 3 essentially differs from the apparatus of Antoni et al in reciting that the end cap is solvent bonded to the housing. Kane et al teach a filter apparatus wherein the end cap is sealed to the housing by adhesive bonding, solvent bonding, thermal fusion, ultrasonic welding or other standard bonding/sealing technique (see col. 4, lines 40-43). It would have been obvious to a person of ordinary skill in the art to attach the end cap of Antoni et al to the housing by known alternative bonding and sealing techniques including solvent bonding.

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16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,916,647 and 4,975,247 and 4,784,768 and Japanese Patent No. 4-231670 and 6,050,278 teach filter apparatus having end caps with multiple ports.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (703) 308-2350. The examiner can normally be reached on weekdays from 7:00 AM - 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker, can be reached on (703) 308-0457. The fax phone number for official response after final action is (703) 872-9311, and the fax phone number for all other official faxes is (703) 872-9310.

When sending a draft amendment by fax, please mark the paper as "DRAFT"; otherwise, mark the paper "OFFICIAL". This will expedite the processing of the paper.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0651.


John Kim
Primary Examiner
Art Unit 1723

J. Kim
February 26, 2003